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Nanotechnology and the Environment

Nine Zeros Nanotechnology
Breakfast Roundtable

October 4, 2004

Nanotechnology and the Environment

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New Dog, Old Tricks

- **Manufacture, processing, use, distribution in commerce and disposal of nanomaterials currently unregulated**
- **Many unknowns concerning potential health and environmental effects**
- **Existing/new regulatory schemes likely will apply; precautions and practical experience gained in other contexts may reduce risk**

TSCA

- **Regulates manufacture and use of "chemical substances"**
  - Manufacturer testing / data collection
  - Pre-manufacture notice (PMN) and EPA review
  - EPA may prohibit, limit, and regulate manufacture/use of chemical substances
- **EPA regulation may not impede technological innovation**

TSCA

- **Chemical substances include:**
  - Existing chemical substances
  - New chemical substances
  - Significant new uses of existing chemical substances

TSCA

- **Threshold question: are nanoparticles "new chemical substances" under TSCA**
  - Nanoparticles are configurations of common elements that are not new chemical substances
  - EPA has expressed doubt that nanomaterials would fall within TSCA's definition of "new chemical substance"

TSCA

- **Manufacture and use of common elements at the nanoscale may constitute a "significant new use"**
  - EPA has indicated it will treat each new category of nanomaterials as a "significant new use"
  - Such a determination would trigger PMN requirement

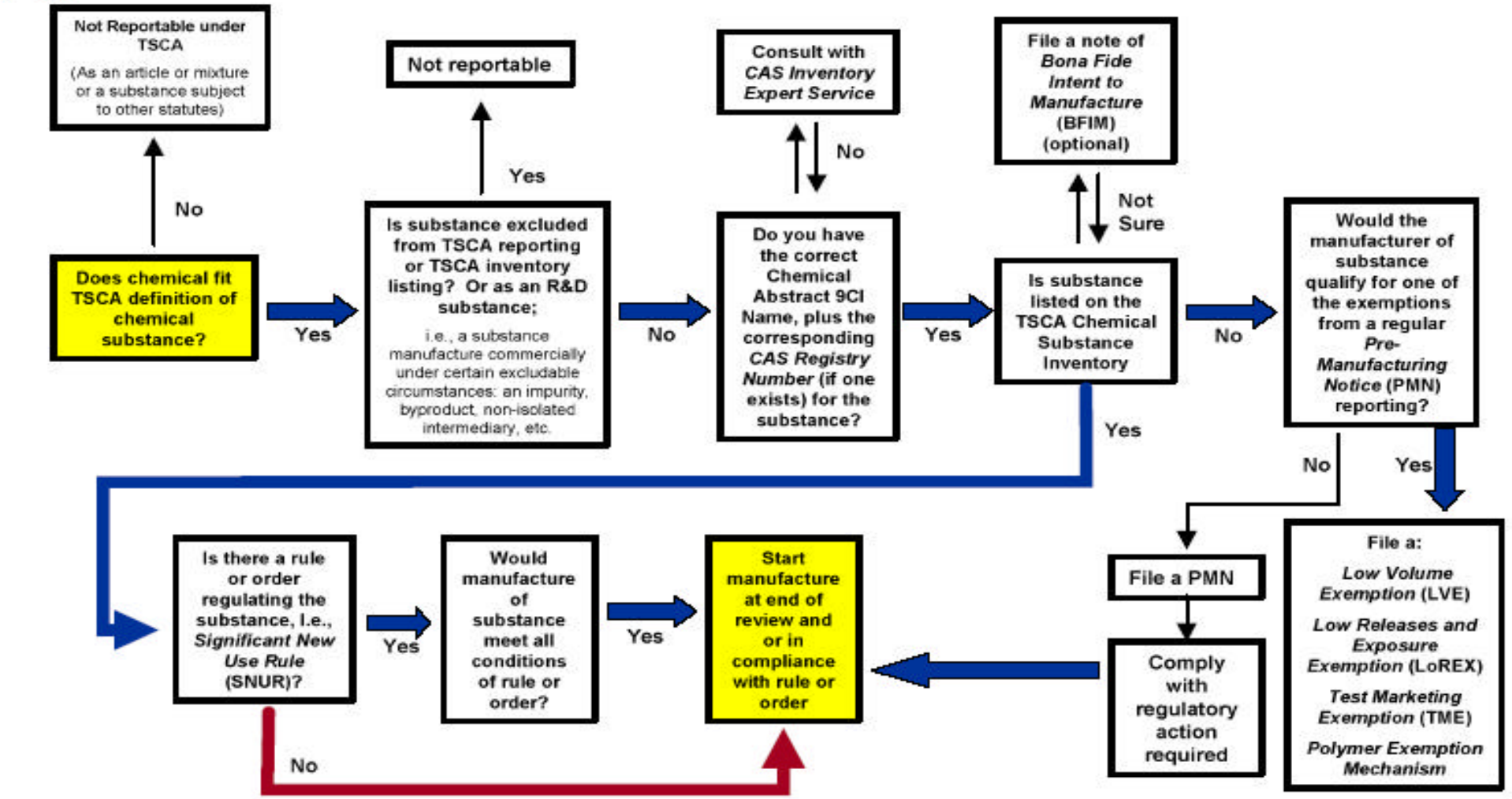
TSCA

- **SNU determination requires EPA to consider:**
  - Projected volume of substance manufactured / processed
  - Change in type or form of human / environmental exposure to substance
  - Extent use increases exposure
  - Reasonably anticipated methods of manufacturing, processing, distribution, and disposal

TSCA

- **Practical considerations assuming nanomaterials regulated as SNUs**
  - Exemptions may apply (LVE, R&D)
  - Notice must include test data in "possession and control"
  - Notice must include description of data "known to the person making the notice or insofar as reasonably ascertainable"

Processing New Chemical Through TSCA



Based on Chart by Ahson Wardak – UVA; Reviewed by EPA

ECTeague NNCO/ NSET/ NSTC

Clean Air Act

- Designation as § 112 Hazardous air pollutant?
- Regulate as PM ≤ 2.5?
- Independent state regulation?

Occupational Safety and Health Act "OSHA"

- **Protects worker health and safety**
  - Sets standards for permissible exposure limits (PEL)
  - Regulations implementing OSHA set standards for personal protective equipment
  - Standards are based on health effects data
  - Does not apply to companies with fewer than 11 employees (Guidance applies)

National Environmental Policy Act (NEPA)

- **Applies to all "major federal actions" having significant affect on environment**
  - Major federal actions include funding
- **Environmental impact review**
  - Assess environmental impacts of proposed projects
    - Consider Alternatives
    - Mitigation measures
- **"Mini-NEPA" state analogs**

California Proposition 65

- **1986 California Law**
- **Reduce exposure to chemicals known to cause cancer or to have reproductive toxicity by:**
  - requiring warnings
  - prohibiting discharge into drinking water

International Considerations: The European Union

- **The European Union**
  - Created in 1993
  - Currently 25 member states, with 4 more pending
  - Membership open to any European country with stable democratic government, good human rights record, functioning market economy, and sound macroeconomic policies
  - European Commission responsible for proposing legislation, and administration and enforcement

European Union – Environmental Protection

- **Sixth Action Program for the Environment**
  - Establishes EU environmental priorities through 2010
  - Four target areas: climate change; nature and biodiversity; environment and health; and management of natural resources and waste
  - Implementation instruments: eco-labeling; environmental inspections; end-of-life vehicles

The Precautionary Principle

- **Develop and implement guidelines to ensure a high level of protection of the environment and of human, animal and plant health whenever the available scientific data do not permit a complete evaluation of the risk**
  - Scientific/objective evaluation identifies potentially dangerous effects of new product/process
  - Evaluation does not allow risk to be determined with sufficient certainty
  - Function of risk considered acceptable by society

EU REACH Proposal

- **Implements Precautionary Principle**
  - Replaces > 40 existing EU directives
  - Requires companies to assess risks arising from chemical use, and take measures to manage risk
  - Manufacture/import of > 1 ton of chemical/year
  - Establishes central database
  - Substances of high concern would require Commission authorization

EU Commission and Nanotechnology

- **Make maximum use of existing regulations to ensure high level of public health, safety, consumer and environmental protection**
  - Nanotechnologies must address any potential risk upfront, as early as possible, on basis of reliable scientific data/analysis
  - Nanotechnology = creation of new chemical
  - Assessment of risk must be integrated into every step of life cycle
  - Potential use of Precautionary Principle

Royal Society & Royal Academy of Engineering Report (July 2004)

- **Environmental Recommendations:**
  - Treat nanoparticles as if hazardous
    - reduce and remove from waste stream
    - establish end-of-life management requirement
  - Assess risk of release through product lifecycle
  - Prohibit use of nanoparticles in environmental applications pending additional research and risk/benefit analysis

Royal Society/Academy Report (cont.)

- **Health Recommendations:**
  - Establish Research Center to:
    - Research toxicity/epidemiology
    - Research persistence in environment and risk of bioaccumulation
    - Develop instruments for monitoring
  - Maintain and share database of results

Royal Society/Report (cont.)

- **Regulatory Recommendations:**
  - Adapt existing regulatory frameworks
    - UK TSCA Analog
      - treat as “new substances”
      - evaluate production thresholds that trigger testing
  - Develop new regulatory framework
    - EU REACH proposal

Royal Society/Academy Report (cont.)

- **Regulatory Recommendations (cont.):**
  - Consider setting lower occupational exposure limits for nanoparticles
  - Review current procedures for accidental release
  - Nanoparticle ingredients in products like sunscreen should undergo safety assessment
  - Manufacturers publish safety assessment methods used
  - Label Consumer products containing nanoparticles

Insurance Implications

- **Swiss Re**
  - Concern over lack of existing regulations
  - Comparison drawn to asbestos, and need to promptly develop consensus on benefits vs. risks
- **Munich Re**
  - Numerous potential liabilities exist: environmental and worker
  - Inability to trace liability to specific manufacturer

What Are Industry Leaders Doing Now?

Implement:

- prudent lab practices
- Education
- Hazard communication

Treat nanomaterials as if hazardous:

- Seek zero emissions
- Apply the same safety management protocols as for hazardous chemicals, and biological and radioactive materials

Facility Siting Considerations

Lawrence Berkeley National Labs Molecular Foundry

"Not even the Environmental Protection Agency knows the impact of these things, but we're ready to let them loose in Berkeley."

Tom Kelly, Berkeley Commission on Health

Public Relations

- **Communication:**
  - Public and policymakers must have access to understandable scientific data
  - Public must be involved to ensure trust and credibility
- **Acknowledge potential risks and promote potential benefits**

Regulatory Development Considerations

- **United States -- Potential Revisions to:**
  - TSCA
    - Imposition of new requirements
    - Applicability of existing exemptions (LVE, R&D)
  - State regulations (California Proposition 65)
- **European Union**
  - Potential revisions to UK TSCA Analog
  - Finalization of REACH Proposal

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